Premarket Notification [510(k)] Summary

OCT - 2 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K062180

Company: Horiba ABX
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Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: 27th July 2006

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA Amylase CP**
Common or Usual Name:	Amylase
Device Class	Class II
Classification Name:	§862.1070 : Amylase Test System
Product Code:	JFJ ; Catalytic methods, Amylase

CALIBRATORS:

Trade/Proprietary Name:	**ABX PENTRA Multical** (K052007)
Common or Usual Name:	Multical
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA N Control** (K052007)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (K052007)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

CLEANING SOLUTIONS:

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem CP** (K052007)
Common or Usual Name:	Cleaning solution : Clean-Chem
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem 99 CP** (K052007)
Common or Usual Name:	Cleaning solution : Clean-Chem 99
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

Submission device	Substantially equivalent Predicate device
ABX PENTRA Amylase CP	K801295
ABX PENTRA Multical	K052007
ABX PENTRA N Control	K052007
ABX PENTRA P Control	K052007

Description:

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA Amylase CP** is an in vitro diagnostic assay for the quantitative determination of alpha-amylase in human serum and plasma based on an enzymatic photometric test. The assay is composed of a bi-reagent cassette, with 26 ml and 6.5 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator with chemical additives and materials of biological origin. The assigned values of the calibrator components are given in the enclosed annex, ensuring optimal calibration of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer.
This calibrator is provided in ten vials of 3 ml.

The **ABX PENTRA N Control** and **ABX PENTRA P Control** are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml.

The **ABX PENTRA Clean-Chem CP** and **ABX PENTRA Clean-Chem 99 CP** are ready-to-use chemical cleaning solutions for use on the ABX Pentra 400 system. They are respectively provided in mono-reagent 30 ml and 4 x 99 ml cassettes.

Intended Use :

The reagent in this submission is intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of alpha-amylase using human serum and plasma.

The controls, calibrators and additional reagents are intended for use in association with the above reagent.

Discussion of Performance Data:

ABX PENTRA Amylase CP :	
Sample type	Serum & plasma
Detection limit	4 U/l
Accuracy and Precision	CV Total < 2.74%
Measuring range	4.5 U/l – 2042 U/l
Upper linearity limit	2000 U/l, and with automatic post-dilution : 6000 U/l
Correlation (n=131)	Y = 1.17 x – 6.23 with a correlation coefficient r^2 = 0.9971.
Calibration stability	8 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 42 days

CALIBRATORS

ABX PENTRA Multical:		
Analytes	Already cleared (K052007)	Included in this submission
Alkaline phosphatase*		
Alanine aminotransferase	√	√
Amylase		√
Aspartate aminotransferase*		
Creatine kinase*		
GGT	√	√
Lactate Dehydrogenase*		
Lipase	√	√
Albumin*		
Direct Bilirubin*		
Total Bilirubin*		
Calcium*		
Cholesterol*		
Creatinine*		
Glucose HK	√	√
Glucose PAP	√	√
Iron*		
Lactic acid	√	√
Magnesium*		
Phosphorus*		
Total Protein*		
Triglycerides*		
Urea / Blood Urea Nitrogen*		
Uric acid*		
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components** are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C **Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C	

* Not cleared as of date of submission

CONTROLS

ABX PENTRA N Control:		
Analytes	Already cleared (K052007)	Included in this submission
Alkaline phosphatase*		
Alanine aminotransferase	√	√
Amylase		√
Aspartate aminotransferase*		
Creatine kinase*		
GGT	√	√
Lactate Dehydrogenase*		
Lipase	√	√
Albumin*		
Direct Bilirubin*		
Total Bilirubin*		
Calcium*		
Chloride	√	√
Cholesterol*		
HDL*		
LDL*		
Creatinine*		
Glucose HK	√	√
Glucose PAP	√	√
Iron*		
Lactic acid	√	√
Magnesium*		
Phosphorus*		
Potassium	√	√
Sodium	√	√
Total Protein*		
Triglycerides*		
Urea / Blood Urea Nitrogen*		
Uric acid*		
		.../...

Format	Lyophilized human serum with chemical additives and materials of biological origin

ABX PENTRA N Control:	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

ABX PENTRA P Control:		
Analytes	Already cleared (K052007)	Included in this submission
Alkaline phosphatase*		
Alanine aminotransferase	√	√
Amylase		√
Aspartate aminotransferase*		
Creatine kinase*		
GGT	√	√
Lactate Dehydrogenase*		
Lipase	√	√
Albumin*		
Direct Bilirubin*		
Total Bilirubin*		
Calcium*		
Chloride	√	√
Cholesterol*		
HDL*		
LDL*		
Creatinine*		
Glucose HK	√	√
Glucose PAP	√	√
Iron*		
Lactic acid	√	√
Magnesium*		
Phosphorus*		
Potassium	√	√
Sodium	√	√
Total Protein*		
Triglycerides*		
Urea / Blood Urea Nitrogen*		
Uric acid*		
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C .../... Total Bilirubin	

	8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

CLEANING SOLUTIONS

ABX PENTRA Clean-Chem CP (Already cleared K052007):	
Format	Chemical liquid solution
Stability	Closed stability: 8 months at 2-8°C On-board stability (refrigerated area): 15 days

ABX PENTRA Clean-Chem 99 CP (Already cleared K052007):	
Format	Chemical liquid solution
Stability	Closed stability: 8 months at 2-8°C On-board stability (refrigerated area): 45 days

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tim Lawton, Regulatory Affairs Manager
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France

OCT - 2 2006

Re: k062180
Trade/Device Name: Amylase on ABX PENTRA 400 Clinical Chemistry Analyzer
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase test system
Regulatory Class: Class II
Product Code: JFJ, JIX, JJY
Dated: July 27, 2006
Received: July 31, 2006

Dear Mr. Lawton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062180

Device Name: Amylase on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

Amylase reagent, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure amylase analyte.

ABX PENTRA Amylase CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of the activity of the enzyme amylase in human serum and plasma based on an enzymatic photometric assay.
Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

...sion Sign-Off

Office of ... Diagnostic Device
Evaluation and Safety

K062180

Indications for Use

510(k) Number (if known): K062180

Device Name: ABX PENTRA Multical

Indications For Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba ABX methods on Horiba ABX clinical chemistry analyzers.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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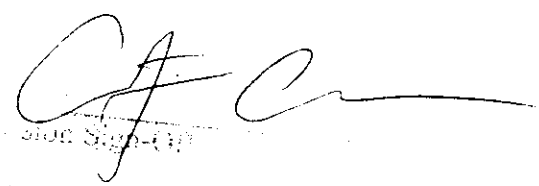
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K062180

Indications for Use

510(k) Number (if known): K062180

Device Name: ABX PENTRA N Control

Indications For Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Diagnostic Devices

K062180

Indications for Use

510(k) Number (if known): K062180

Device Name: ABX PENTRA P Control

Indications For Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Diagnostic Devices

K062180